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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/052,855 03/31/98 BILLING-MEDEL

P 6064.US.P1

023492  
ABBOTT LABORATORIES  
DEPT. 377 - AP6D-2  
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ABBOTT PARK IL 60064-6050

HM22/1023

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/23/01

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/052,855

Applicant(s)

Billings-Medel et al

Examiner

Karen Canella

Art Unit

1642



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9, 17-24, 26-29, 31-34, 36, 37, and 44-58 is/are pending in the application.
- 4a) Of the above, claim(s) 1-9, 17-24, 26-29, 31-34, 36, and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

***Response to Amendment***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 10-16, 25, 30, 35 and 38-43 have been canceled. Claims 44-58 have been added. Claims 1-9, 17-24, 26-29, 31-34, 36, 37, and 44-58 are pending. Claims 1-9, 17-24, 26-29, 31-34, 36 and 37 are withdrawn from consideration. Claims 44-58 are under consideration.

***Claim Rejections Maintained***

3. The rejection of newly added claims 44-58 under 35 U.S.C. 101, because the claimed invention is not supported by either a credible, specific and substantial utility, or a well-established utility is made for reasons of record.
4. The rejection of newly added claims 44-58 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is made for reasons of record.
5. Applicant argues that the claimed polynucleotides have utility based on tissue specific expression in the prostate and that the claimed polynucleotides can be used to diagnose prostate disease when detected outside of the normal parenchyma. This has been considered but not found persuasive as the specification does not teach that the claimed polynucleotides would be present in, for example, metastatic prostate cells. It is well known in the art that metastatic cancer cells have altered patterns of gene expression in comparison with the non-metastatic precursor cancer cell. For instance, metastatic breast cancer cells are negative for E-cadherin expression, while normal breast cells and non-invasive breast cells are positive (Oka et al, Cancer Research, 1993, vol. 53, pp. 1696-1701). Therefore, it cannot be predicted that the claimed polynucleotides would be expressed in metastatic prostate cancer cells. Furthermore, claims 49, 50, 52, 54, 55 and 58 are drawn to polynucleotides encoding an epitope, a polypeptide, or a method for producing a polypeptide and the specification does not provide evidence the claimed polynucleotides are actually translated into a polypeptide marker that would be useful in the

detection of prostate cancer or other prostate disease, for the reasons of record stated in the previous office action.

6. All other rejections and objections as stated in Paper No. 30 are withdrawn.


***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
October 8, 2001

  
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